

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

At the outset, Applicants wish to address the showing required under 37 CFR § 1.116(a) regarding why the amendments above are necessary and were not presented earlier. The amendments above to claims 1,3-6, 11 and 12, are necessary to provide a clear line of distinction between the cited prior art and the instant claims. The amendments were not presented earlier because Applicants believed that the previous limitation to "dermatological topical" was sufficient for this purpose. The Examiner points out that this statement of intended use is being ignored, but Applicants do not believe it is possible to ignore the "water-in-oil" limitation, as it is structural. In view of the foregoing, Applicants respectfully request that the Examiner enter and consider the amendments above.

Regarding the restriction requirement, the Examiner finds that Applicants elected Group I without traverse. Applicants dispute this, and point out that the Office Action dated May 26, 1999, required Applicants to affirm their oral election, and the affirmation in the amendment dated November 24, 1999, was of an election with traverse. Applicants believe, therefore, that the election must be taken as one with traverse.

In any case, the Examiner finds that if product claims are found allowable, then method

claims incorporating the allowable products will be rejoined and considered. In order to facilitate this, Applicants have replaced claim 2 by new method claim 13, which is dependent upon product claim 1.

Claims 1 and 3 were rejected under 35 USC § 103(a) as being obvious over Kohmura et al. ("Kohmura"), Agric. Biol. Chem., 54: 835-836 (1990). The Examiner again finds that persons skilled in the art would have been motivated, given Kohmura, to prepare a pharmaceutical composition comprising peptides of Kohmura as an active ingredient therein because Kohmura teaches that these peptides inhibit ACE activity and therefore may be useful in treatment of ACE-mediated processes, such as regulation of blood pressure. In response, Applicants point out that such theory, logically extended, at best suggests formulation of Kohmura's peptides as oral or parenteral formulations. However, oral or parenteral formulations are usually oil-in-water-formulations which can be resorbed by the mucosa very easily since the outer or continuous phase is aqueous. Oral or parenteral formulations are never water-in-oil-based formulations since the outer oily phase is incompatible with the mucous (=aqueous !) membranes. Accordingly, in order to provide a clear distinction between what the Examiner finds Kohmura suggests, and what is claimed, Applicants have amended the claims to require "water-in-oil" preparations, in accordance with the specification at page 21, lines 24-25, and, for example, Examples 1 and 2. In view of this limitation, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Claims 1 and 3 were rejected under 35 USC § 103(a) as being obvious over Kohmura in view of Atlas of Protein Sequence and Structure (Vol. 5, 1972). In response, Applicants point again to the defects of Kohmura which are noted above. The "Atlas" was cited only to show certain conservative substitutions for Val, and, therefore, does not cure any of the defects of Kohmura. Accordingly, the cited combination of references cannot render obvious the rejected claims, and Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

Claims 1, 3 and 4 were rejected under 35 USC § 103(a) as being obvious over Kohmura in view of Bundgaard (Design of Prodrugs, Chapter 1, 1985) and Sumner-Smith, U.S. Patent No. 5,646,120. In response, Applicants point again to the defects of Kohmura which are noted above. Bundgaard is cited to show administration of peptides in the form of prodrugs, and Sumner-Smith is cited to show the use of the acetyl group to protect the amino terminal group, and the use of amido to protect carboxyl terminal group. Consequently, neither Bundgaard nor Sumner-Smith cures any of the defects of Kohmura. Accordingly, the cited combination of references cannot render obvious the rejected claims, and Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

Claims 1 and 3 were rejected under 35 USC § 102(e) as being anticipated by Steffens et al. ("Steffens"), U.S. Patent No. 5,681,721. In response, Applicants point out that the instant claims are drawn to "[c]osmetic or dermatological topical water-in-oil preparations." The

compositions of Steffens appear to be injectable aqueous formulations. See Steffens at column 6, lines 1-2. Accordingly, there is no anticipation. therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Claims 1 and 3 were rejected under 35 USC § 103(a) as being obvious over Steffens in view of Atlas or Protein Sequence and Structure (Vol. 5, 1972). In response, Applicants point again to the defects of Steffens which are noted above. The "Atlas" was cited only to show certain conservative substitutions for Val, and, therefore, does not cure any of the defects of Steffens. Accordingly, the cited combination of references cannot render obvious the rejected claims, and Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

Claims 1 and 6 were rejected under 35 USC § 103(a) as being obvious over Kohmura or Steffens. In response, Applicants point again to the defects of Kohmura and Steffens which are noted above. To the extent that there are concentration differences between the instant claims and the formulations of Kohmura or Steffens, then these would be in addition to the defects noted above, which are not bridged by any cited reference. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

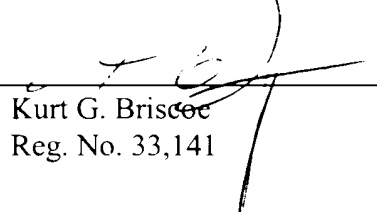
Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (914) 332-1700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Hon. Commissioner of Patents, Washington, D.C. 20231, on the date indicated below:

Date: September 13, 2000

By 
Kurt G. Briscoe